APR 1 8 2000

K000245

510(k) SUMMARY

Conway Stuart Medical, Inc.'s
CSM Stretta™ System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Conway Stuart Medical, Inc.
735 Palomar Avenue
Sunnyvale, California 94086

Contact Person:

Thomas C. Wehman
Regulatory Affairs
Conway Stuart Medical, Inc.
735 Palomar Avenue
Sunnyvale, California 94086

Date Prepared: January 27, 2000

Name of Device

CSM Stretta™ System

Common or Usual Name

RF generator and electrosurgical accessories

Classification Name

Electrosurgical cutting and coagulation device and accessories

Predicate Devices

1. CSM Stretta Model C8 Needle Inflatable Basket Catheter Electrode with Aspiration
2. CSM Stretta Control Module Model S400 RF Electrosurgical Generator
3. CSM Stretta Catheter

4. Snowden Pencer Nissen Laparoscopic Instrumentation

Intended Use

Intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).

Substantial Equivalence

The Stretta System is substantially equivalent to other marketed devices that have received premarket clearance, including Conway Stuart's S400 Generator (K991529), Conway Stuart's Stretta Catheter (K983116), Conway Stuart's Stretta Catheter with Aspiration (K991291), and Snowden Pencer's Nissen Laparoscopic Instrumentation (K930667). The Stretta System has the same general intended use as the previously cleared Conway Stuart devices, the same specific intended use as the Snowden Pencer Nissen Laparoscopic Instrumentation, and very similar principles of operations and technological characteristics as the previously cleared Conway Stuart devices.

An open-label, single arm, non-randomized clinical study was performed to evaluate safety and efficacy of the Stretta system for the treatment of gastro-esophageal reflux disease (GERD). Forty-seven patients in six clinical sites were enrolled, treated, and followed for six months. The results of the clinical study demonstrate that quality of life improvements with the Stretta were statistically and clinically significant and were comparable to those achieved with medication and fundoplication. Esophageal pH improvements were also clinically significant and the safety of the Stretta is equivalent to that of fundoplication as reported in the literature.

Overall, the clinical study results show that patients tolerate the Stretta treatment of GERD well without general anesthesia, with shorter hospital stay, and with less recovery time compared to published reports on fundoplication. Thus, the clinical data show that the Stretta device is safe and effective for treatment of GERD and the risk-benefit profile is substantially equivalent to that of fundoplication surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2000

Conway Stuart Medical, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K000245
Trade Name: CSM Stretta System
Regulatory Class: II
Product Code: GEI
Dated: January 27, 2000
Received: January 27, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000245

STRETTA™ SYSTEM INDICATIONS FOR USE:

The Stretta™ System is intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of Gastroesophageal Reflux Disease (GERD).

Donna R. Vochmer

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